

# UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.  
59533(49397)

Total Pages in this Submission  
25

## TO THE COMMISSIONER FOR PATENTS

Mail Stop Patent Application  
P.O. Box 1450  
Alexandria, VA 22313-1450

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

**METHODS AND COMPOSITIONS FOR REDUCING THE RISK ASSOCIATED  
WITH THE ADMINISTRATION OF OPIOID ANALGESICS IN PATIENTS WITH  
DIAGNOSED OR UNDIAGNOSED RESPIRATORY ILLNESS**

22141 U.S. PTO  
10/661458

09/10/03

and invented by:

Gary W. Pace  
Maree T. Smith

If a **CONTINUATION APPLICATION**, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: \_\_\_\_\_

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: \_\_\_\_\_

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: \_\_\_\_\_

Enclosed are:

### Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 25 pages and including the following:
  - a. ☒ Descriptive Title of the Invention
  - b. ☐ Cross References to Related Applications (if applicable)
  - c. ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
  - d. ☐ Reference to Sequence Listing, a Table, or a Computer Program Listing Appendix
  - e. ☒ Background of the Invention
  - f. ☒ Brief Summary of the Invention
  - g. ☒ Brief Description of the Drawings (if filed)
  - h. ☒ Detailed Description
  - i. ☒ Claim(s) as Classified Below
  - j. ☒ Abstract of the Disclosure

**UTILITY PATENT APPLICATION TRANSMITTAL**  
**(Small Entity)**

*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

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**Application Elements (Continued)**

3. ☐ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
- a. ☐ Formal      Number of Sheets \_\_\_\_\_
- b. ☐ Informal      Number of Sheets \_\_\_\_\_
4. ☐ Oath or Declaration
- a. ☐ Newly executed *(original or copy)*      ☐ Unexecuted
- b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
- c. ☐ With Power of Attorney      ☐ Without Power of Attorney
- d. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting inventor(s) named in the prior application,  
see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference *(usable if Box 4b is checked)*  
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ CD ROM or CD-R in duplicate, large table or Computer Program (Appendix)
7. ☐ Application Data Sheet (See 37 CFR 1.76)
8. ☐ Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all must be included)*
- a. ☐ Computer Readable Form (CFR)
- b. ☐ Specification Sequence Listing on:
- i. ☐ CD-ROM or CD-R (2 copies); or
- ii. ☐ Paper
- c. ☐ Statement(s) Verifying Identical Paper and Computer Readable Copy

**Accompanying Application Parts**

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(B) Statement (when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement/PTO-1449      ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☒ Certificate of Mailing
- ☐ First Class      ☒ Express Mail *(Specify Label No.):* EV 343735197 US

*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

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17. ☒ Applicant claims small entity status. See 37 CFR 1.27.

☐ (Optional) Small Entity Statement(s) - Specify Number of Statements Submitted:

18. ☐ Additional Enclosures (please identify below):

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19. ☐ Pursuant to 35 U.S.C. 122(b)(2), Applicant hereby requests that this patent application not be published pursuant to 35 U.S.C. 122(b)(1). Applicant hereby certifies that the invention disclosed in this application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing of the application.

***An applicant who makes a request not to publish, but who subsequently files in a foreign country or under a multilateral international agreement specified in 35 U.S.C. 122(b)(2)(B)(i), must notify the Director of such filing not later than 45 days after the date of the filing of such foreign or international application. A failure of the applicant to provide such notice within the prescribed period shall result in the application being regarded as abandoned, unless it is shown to the satisfaction of the Director that the delay in submitting the notice was unintentional.***

09/10/03

47364 U.S. PTO

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## Fee Calculation and Transmittal

### CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	23	- 20 =	3	x \$9.00	\$27.00
Indep. Claims	4	- 3 =	1	x \$42.00	\$42.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$375.00
OTHER FEE (specify purpose) _____					\$0.00
TOTAL FILING FEE					\$444.00

- ☐ A check in the amount of \_\_\_\_\_ to cover the filing fee is enclosed.
- ☐ The Director is hereby authorized to charge and credit Deposit Account No. \_\_\_\_\_ as described below.
- ☐ Charge the amount of \_\_\_\_\_ as filing fee.
  - ☐ Credit any overpayment.
  - ☐ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
  - ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: September 10, 2003



Signature

Daniel F. Coughlin, Reg. No. 36,111  
Intellectual Property Practice Group  
Edwards & Angell  
P.O. Box 9169  
Boston, MA 02209  
Tel: (203)975-7505

cc:

**CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)**

Applicant(s): Gary W. Pace and Maree T. Smith

Docket No.

59533(49397)

Serial No.

Not yet Assigned

Filing Date

Filed herewith

Examiner

Not Yet Assigned

Group Art Unit

Not Yet Assigned

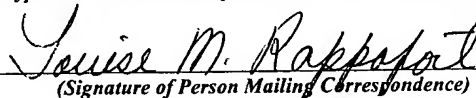
Invention:

**METHODS AND COMPOSITIONS FOR REDUCING THE RISK ASSOCIATED WITH THE  
ADMINISTRATION OF OPIOID ANALGESICS IN PATIENTS WITH DIAGNOSED OR  
UNDIAGNOSED RESPIRATORY ILLNESS**

I hereby certify that the following correspondence:

**NEW UTILITY PATENT APPLICATION***(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

September 10, 2003*(Date)*Louise M. Rappaport*(Typed or Printed Name of Person Mailing Correspondence)**(Signature of Person Mailing Correspondence)*EV 343735197 US*("Express Mail" Mailing Label Number)***Note: Each paper must have its own certificate of mailing.**